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| APPLICATION NO. | F | ILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|---|------------|---------------------|----------------------|------------------------|-----------------|
| 10/807,888 | 03/24/2004 | | David J.S. Kim | P11111.00 | 5592 |
| 27581 | 7590 | 10/11/2006 | | EXAMINER | |
| MEDTRON | • | | LUSTUSKY, SARA | | |
| 710 MEDTE | | ARK N 55432-9924 | | ART UNIT PAPER NUMBER | |
| 141111111111111111111111111111111111111 | , 213, 111 | | | 3735 | |
| | | | | DATE MAILED: 10/11/200 | 6 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | C | | | | | |
|--|--|---|------|--|--|--|--|--|
| | Application No. | Applicant(s) | | | | | | |
| | 10/807,888 | KIM ET AL. | | | | | | |
| Office Action Summary | Examiner | Art Unit | | | | | | |
| | Sara Lustusky | 3735 | | | | | | |
| The MAILING DATE of this communication app Period for Reply | pears on the cover sheet w | vith the correspondence address | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING D. - Extensions of time may be available under the provisions of 37 CFR 1.1: after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period v. - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUN 36(a). In no event, however, may a will apply and will expire SIX (6) MO , cause the application to become | ICATION. The reply be timely filed ONTHS from the mailing date of this communication ABANDONED (35 U.S.C. § 133). | | | | | | |
| Status | | | | | | | | |
| 1) Responsive to communication(s) filed on | <u>_</u> . | | | | | | | |
| | · | | | | | | | |
| • • • | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | | |
| closed in accordance with the practice under E | x parte Quayle, 1935 C. | D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | i | | | | | | | |
| 4) Claim(s) 1-36 is/are pending in the application. | | | | | | | | |
| 4a) Of the above claim(s) is/are withdraw | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | |
| 5) Claim(s) 31-36 is/are allowed. | | | | | | | | |
| , | ☐ Claim(s) 1,10-12,15,18-22,25 and 30 is/are rejected. | | | | | | | |
| , — | (i) Claim(s) 2-9,13,14,16,17,23,24 and 26-29 is/are objected to. | | | | | | | |
| 8) Claim(s) are subject to restriction and/o | r election requirement. | | | | | | | |
| Application Papers | | | | | | | | |
| 9) The specification is objected to by the Examine | er. | | | | | | | |
| 10)⊠ The drawing(s) filed on 24 March 2004 is/are: | a)⊡ accepted or b)⊠ o | bjected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the | | | | | | | | |
| Replacement drawing sheet(s) including the correct | | | (d). | | | | | |
| 11)☐ The oath or declaration is objected to by the Ex | caminer. Note the attach | ed Office Action or form P1O-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | | | |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: | priority under 35 U.S.C. | § 119(a)-(d) or (f). | | | | | | |
| 1. Certified copies of the priority document | s have been received. | | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | | | |
| Copies of the certified copies of the prior | | n received in this National Stage | | | | | | |
| application from the International Burea | • | . No. of the second | | | | | | |
| * See the attached detailed Office action for a list | of the certified copies no | ot received. | | | | | | |
| Attachment(s) | . | | | | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper N | v Summary (PTO-413) o(s)/Mail Date | | | | | | |
| 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 3/24/04, 2/09/06. | 5) Notice of Other: | f Informal Patent Application | | | | | | |

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DETAILED ACTION

Specification

- 1. The abstract of the disclosure is objected to because it exceeds the 150 word limit. Correction is required. See MPEP § 608.01(b).Applicant is reminded of the proper language and format for an abstract of the disclosure.
- 2. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited.
- 3. The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Drawings

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: (53) as seen in Figure 4. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective

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action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 6. Claims 1, 10-11, 13, 16, 18-21, 25 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Paul et al. (Patent 6758808).
- 7. Paul et al. teaches a suction-assisted tissue-engaging device and method of using comprising:
 - an elongated articulating arm (30) extending between an articulating arm proximal end and an articulating arm distal end enclosing an arm vacuum lumen (710) coupled with a vacuum port where the vacuum source is attached to the distal portion of the vacuum lumens (710 or 770) (as seen in Figure 15A), the articulating arm (30) adapted to be manipulated in a flexible state into an operative shape and changed into a rigid state maintaining the operative shape (as described in lines 64-67 of column 3 and in lines 1-2 of column 4);

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b. a suction member (20, 600) coupled to the articulating arm distal end having a suction member vacuum lumen (618, 708) coupled with the arm vacuum lumen (710) extending to at least one suction port (632) adapted to be applied against the body organ (as seen in the embodiments in Figures 14A-G and 15A-B) (as described in lines 7-24 of column 5; in lines 50-67 of column 11 and lines 1-13 of column 12);

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- c. an elongated flexible outer sheath (460, 760) having a lumen (as described in lines 29-36 of column 4) extending between an outer sheath distal end coupled to the suction member (20, 600) and an outer sheath proximal end coupled to the articulating arm proximal end (a seen in the embodiments in Figures 10F and 15A) (as described in lines 51-62 in column 21);
- d. a plurality of interlocking articulating links within the outer sheath lumen, the links each having a proximal end and distal end and a link bore and an elongated tensioning cable extending through the articulating link bores(770), whereby the aligned link bores provide the arm vacuum lumen (710 or 770) alongside the elongated tensioning cable (288) (as seen in Figures 4 and 15A) (as described in lines 32-42 of column 14);
- e. tensioning means coupled to the cable proximal end that is selectively operable to release tension in the cable and to impart tension in the cable to manipulate the links produce a flexible and rigid state in the articulating arm (as described in lines 36-39 in column 3); and

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f. wherein the suction member (600) further comprises a suction pad diverging into a plurality of flexible appendages (602, 604) each having at least one suction port (608, 610) coupled to the suction member vacuum lumen (at 616, 618) and adapted to be applied against body tissue and shaped to conform to an area of a body organ (as seen in Figures 14A-G), and able to move an organ into a non-physiological position;

- g. wherein the distal suction member further comprises: a suction member sub-assembly coupled to the cable distal end incorporating the suction member vacuum lumen coupled with the arm vacuum lumen and supporting first and second suction pods to extend distally substantially in parallel and spaced apart from one another each having at least one suction port coupled to the suction member vacuum lumen (as seen in Figures 14A-15B); and
- h. a suction member outer sealing sleeve extending over at least a portion of the suction member sub-assembly sealing the suction member vacuum lumen from vacuum leakage (as seen in Figure 15A).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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9. Claims 12, 14-15, 17 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul et al. (Patent 6758808) as applied to claims 1 and 21 above, in view of Gannoe et al. (PGPUB 2002/0077532 A1).

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- 10. Paul et al. teaches a suction-assisted tissue-engaging device and method of using comprising: an elongated articulating arm, a suction member coupled to the articulating arm, wherein the suction member further comprises a suction pad diverging into a plurality of flexible appendages each having at least one suction port coupled to the suction member vacuum lumen and adapted to be applied against body tissue and shaped to conform to an area of a body organ, as described above. However, Paul et al. does not teach that the suction member appendages spread apart when suction is applied.
- elongated articulating arm (204), a vacuum source (281) coupled with a vacuum port coupled to the articulating arm (204) (as seen in Figures 29-30), the articulating arm (204) adapted to be manipulated in a flexible state into an operative shape and changed into a rigid state maintaining the operative shape (as seen in Figures 16-19 and 25-26); a suction member (280) coupled to the articulating arm (240), wherein the suction member (280) has first and second distally extending stabilizer pods each having at least one suction port (284) coupled to the suction member vacuum lumen; and spreading means operable when suction is applied through the suction ports to the body tissue and responsive to tension imparted to the tensioning cable to render the

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articulating arm in the rigid state for spreading the stabilizer pods apart (as described in paragraphs [0086] and [0100]-[0102]) (as seen in Figures 31-34).

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12. It would have been obvious to one of ordinary skill in the art at the time of the invention to use spreadable appendages or pods similar to those taught by Gannoe et al. on a suction member similar to that taught by Paul et al. because spreadable appendages or pods on a tissue-engaging device provide the advantage of supplying the necessary displacement at the adjacent structure during surgery without changing the ability to stabilize the target site in the desired fashion such that adjacent structures can be retracted to improve access and/or exposure (as described in lines 3-7 of paragraph [0102] of Gannoe et al.).

Allowable Subject Matter

- 13. Claims 2-9, 23-24 and 26-29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
- 14. Claims 2-9, 23-24, 26-29 and 31-36 are allowable over the prior art because none of the prior art of record shows a device and method of using the device to apply suction to body tissue, wherein the device has an elongated articulating arm enclosing a vacuum lumen, wherein the articulating arm exhibits a vacuum leak from the arm vacuum lumen when in a flexible state and wherein the vacuum leak is sealed by changing the articulating arm into a sealed state.

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Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Spence (Patents 6338712 B2, 6019722 and 6610008 B1) show an articulating arm with a vacuum lumen.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sara Lustusky whose telephone number is (571) 272 8965. The examiner can normally be reached on M-F: 9 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272 4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sous Lustusty S.L. Charles A Marmar, I STE, Art Unit 3735